PROCEDURES

Office of Business Informatics

CDER System of Record

Table of Contents

PURPOSE

This MAPP documents CDER's System of Record (SOR) and outlines the policies and procedures for its governance. This includes the following:

- Definition of a Record and SOR
- Identification of the various systems within CDER that holds the SOR
- Listing of the SOR attributes for the identified CDER systems

BACKGROUND

CDER is improving its informatics infrastructure by consolidating data management, business process management and business intelligence. Because of these improvements, legacy systems will be retired, and a modern informatics platform will be established, serving as the new SOR.

During this transition, it is critical to document what the SOR is at any given point in time. Per 36 CFR 1236.10, What Records Management Controls Must Agencies Establish for Records in Electronic Information Systems, this is part of the controls necessary to protect the reliability, authenticity, integrity, usability, content, context and structure of the Federal records contained within the SOR so they can provide adequate and proper documentation of Agency business for as long as the information is needed, (i.e., per their approved retention period in the FDA and CDER records control schedules). In turn, the SOR helps to fulfill

CDER's records management obigations under 44 U.S.C. 3301, Records Management by Federal Agencies.

A **System of Record** (SOR) is the authoritative data source for a given data element or piece of information within an information management system. This definition, although consistent with the Freedom of Information and Privacy Act, is specific to CDER's information technology strategy and infrastructure.

RESPONSIBILITIES

CDER OBI / Program Management Office (PMO)
- Documents the SOR
- Provides guidance for the use of SOR for various systems' implementation
- Maintains and updates the SOR for CDER
- Preforms regular quality assurance checks.

PROCEDURES

1. The System of Record table is validated and updated annually.

2. Updates to the System of Record table are communicated regularly via OBI's standard procedures.

3. The ongoing updates to the SOR table are in alignment with CDER MAPPs, FDA Staff Manual Guides, and FDA and CDER Records Control Schedules.

Quality Assurance: Comprehensive procedures, which perform ongoing data quality checks, to ensure the SOR is up to date.

Conflict Resolution: Key stakeholders will take reasonable steps to reach alignment on unresolved issues. The principles of CDER MAPP 4151.8, *Equal Voice*, and MAPP 4151.2, *Resolution of Differing Professional Opinions: Review by Ad Hoc Panel and Center Director* will be employed to resolve issues, as appropriate.

REFERENCES

1. OMB, Circular A-130, Revised. Management of Federal Information Resources.
2. Clinger – Cohen Act, 40 USC 1401 et seq., 1996.
3. FDA, 2013. Staff Manual Guide 1270.2, Office of Strategic Programs.
4. FDA, 2004. Staff Manual Guide 2010.3. FDA Data Standards Council.
5. FDA, 2004. Staff Manual Guide 3210.2. IT Investment Management.
6. FDA, 2004. Staff Manual Guide 3210.3. IT Project Management Policy.
7. FDA, 2004. Staff Manual Guide 3230.2. Enterprise Architecture Policy.

8. FDA, 2007. Staff Manual Guide 3251.1. Information Resource Management – Information Technology Security.
9. FDA, 2008. Staff Manual Guide 3291.1 Records Management Policy
10. FDA, 2010, Center for Drug Evaluation and Research, MAPP 4151.8 Equal Voice: Discipline and Organizational Component.
11. FDA, 2010, Center for Drug Evaluation and Research, MAPP 4151.2, Rev. 1, Resolution of Differing Professional Opinions: Review by Ad Hoc Panel and Center Director.
12. FDA, 2013, Center for Drug Evaluation and Research, MAPP 7600.8, Rev. 1, CDER Informatics Governance Process.
13. FDA, 2013, Center for Drug Evaluation and Research, MAPP 7600.10, CDER Master Data Management.
14. 44 U.S.C. 2901, Records Management by the Archivist of the United States.
15. 44 U.S.C 3301, Records Management by Federal Agencies.
16. 36 CFR 1236, Electronic Records Management.
17. 36 CFR 1236.10, What Records Management Controls Must Agencies Establish for Records in Electronic Information Systems.

DEFINITIONS

Record: **An item (or) a collection of data. This also** represents a single, implicitly structured data item in a table. Also per 44 U.S.C. 3301 – Records Management By Federal Agencies (The Federal Records Act), "includes all books, papers, maps, photographs, machine-readable materials, or other documentary materials, regardless of physical form or characteristics, made or received by an agency of the U.S. Government under Federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations or other activities of the Government or because of the informational value of the data in them",

Records Management: The planning, controlling, directing, organizing, training, promoting, and other managerial activities related to the creation, maintenance and use, and disposition of records to achieve adequate and proper documentation of Federal policies and transactions and ensure effective and economical management of agency operations. (44 U.S.C. 2901)

System of Record: The authoritative data source for a given data element or piece of information within an information management system. (Per 36 CFR 1236.2, an electronic information system is a "system that contains and provides access to computerized Federal records and other information.").

Master Data: Master Data is a centralized, single source of business data used across multiple systems, and applications processes. Master data may include data about product, sponsor, application, or facility.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
9/29/2014	n/a	Initial issuance.

ATTACHMENT 1 – System of Record Table

System of Record (SOR)	Data Elements and Information	Sample Records
DARRTS	Metadata for Applications Submissions and Supporting documents	Congressional reporting, Performance reporting
Documentum	Work Products	Reviews, Controlled correspondences, Sponsor communications
Electronic Document Room (EDR)	Electronic submissions	Incoming CDER electronic submissions, Applications, Supplements, Master files, Annual reports
FAERS	Event Data	Post-marketing adverse event reports
Integrity	Master Data	*Facility:* Manufacturing Facilities, Clinical Sites, Third party logistics providers, Compounding sites, Wholesale distributors *Product*: Domestic & Foreign Prescription drugs, Over the counter drugs (OTC), Unapproved drugs, Compounded drugs, Ingredients (Active & Inactive) *Sponsor:* New Drug Application holder, Generic Drug Application holder, Drug Master File
Mercado	Regulatory Reporting and Analytics	Pharmaceutical quality reporting
Panorama	Work flow Metadata Work Products	Review/Inspection Status & Outcome, Assignments, Warning letters Application/Supplement/Final labeling/Quality Reviews, Responses to citizen petitions/Congressional inquiries, Approval letters, Sponsor communications